

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

semaglutide (Wegovy)
Novo Nordisk Canada Inc.

Indication: Weight management

September 2, 2021

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	SR0725-000	
Brand name (generic)	semaglutide	
Indication(s)	Obesity management, weight management	
Organization	Obesity Canada - Obésité Canada and the Canadian Association of Bariatric Physicians and Surgeons	
Contact information ^a	Name: Tasneem Sajwani, MD, MBBS, CCFP, FCFP, Dip. ABOM	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>We do not agree with the draft recommendations because:</p> <ul style="list-style-type: none"> The draft recommendation (page 3, "rationale for the recommendation") states that the benefits of semaglutide for obesity management goes beyond the clinically significant threshold of 5% weight reduction. Semaglutide treatment has proven benefit for metabolic conditions and complications of obesity. There is clear evidence of reversal of prediabetes with semaglutide treatment in combination with behavioural change strategies, that cannot be maintained with lifestyle strategies alone for the majority of patients. Additionally, there is alignment of the STEP trials in terms of clinically significant improvement in dyslipidemia, glucose, blood pressure and CRP that is aligned with the causal influence of obesity on cardiovascular risk (https://doi.org/10.1093/eurheartj/ehab454.) The beneficial improvement in these metabolic markers cannot simply be attributed to GLP1-a augmentation of beta-cell function. While future studies are needed to definitively demonstrate improvement in metabolic complications of obesity such as sleep apnea, cirrhosis, type 2 diabetes complications, and major adverse cardiac events, the draft recommendation disregards the likely therapeutic benefit of effectively treating the chronic progressive disease of obesity leaving many patients without access to safe and effective treatment options. 		
Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

The evidence demonstrates that semaglutide should be used as an option to treat the chronic disease of obesity. The data supports that this treatment is statistically and clinically effective at the well-established threshold of 5% weight reduction. The committee needs to clarify what they would consider an effective obesity treatment and acknowledge the broad body of literature demonstrating that weight loss improves complications of the chronic disease of obesity. Semaglutide should be assessed like previous drugs for chronic medical conditions. The draft recommendation appears to be biased against obesity as a chronic disease and thus biased against people living with obesity.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

^a CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.
- For conflict of interest declarations:
 - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
 - Please note that declarations are required for each clinician that contributed to the input.
 - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> • David C W Lau • Stephen Glazer • David Macklin • Mary Forhan • Yvonne B. Kangong • Sabrina Kwon • Rachel Capron • Ryan Oughtred • Sean Wharton • Andrea Milne-Epp • Michael Mindrum 		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Tasneem Sajwani

Position	<i>Family Medicine Physician</i>
Date	<i>06-09-2022</i>
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Novo Nordisk</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Bausch</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Declaration for Clinician 2

Name: David C W Lau, MD, PhD, FRCPC

Position: Professor of Medicine, University of Calgary Cumming School of Medicine

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for David C W Lau

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk	X			
Bayer	X			
HLS Therapeutics	X			
BI	X			
CCRN	X			
CME at Sea	X			
Eli Lilly	X			
Novartis	X			
Pfizer	X			
Viatrix	X			
Pfizer	X			

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 3

Name: Stephen Glazer

Position: Physician

Date: 20/02/2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Stephen Glazer]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk	x			
Bausch	x			
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 4

Name: David Macklin

Position: Medical Director Medcan weight management program/Lecturer U of T

Date: 18th February 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [David Macklin]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk				X
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 5

Name: Mary Forhan

Position: Scientific Director, Obesity Canada

Date: 22/02/2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Mary Forhan]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk	X			

Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 6

Name: Yvonne B. Kangong
Position: Family / Obesity Dr.
Date: March 27, 2027

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Yvonne B. Kangong]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk	X			
Bausch	X			
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 7

Name: Sabrina Kwon
Position: Physician - Diplomate ABOM, Assistant Clinical Professor U of A
Date: March 30, 2027

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Dr. Sabrina Kwon]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk		X		
Bausch	X			
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 8

Name: Rachel Capron
Position: Registered Dietitian, CDE CBE
Date: March 30, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Rachel Capron]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk	X			
Bausch				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 9

Name: Ryan Oughtred

Position: Licensed Naturopathic Doctor in BC, CNPBC#00466

Date: March 30, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Ryan Oughtred]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 10

Name: Sean Wharton

Position: Internal Medicine Physician at Hamilton Health Sciences, Medical Director Wharton Medical Clinic - Obesity and Diabetes Management Clinic

Date: March 30, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Sean Wharton]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk			X	
Bausch			X	
Eli Lilly		X		

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 11

Name: Andrea Milne-Epp

Position: Family Physician, CCFP, ABOM, Clinical Associate Professor University of Alberta

Date: March 31, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Andrea Milne-Epp]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Add company name				
Add or remove rows as required				

* Place an X in the appropriate dollar range cells for each company.

Declaration for Clinician 12

Name: Michael Mindrum, MD, FRCPC

Position: Internal Medicine Physician

Date: March 31, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Michael Mindrum]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk			X	

* Place an X in the appropriate dollar range cells for each company.

Declaration 13

Name: Obesity Canada

Position: n/a

Date: March 31, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Obesity Canada]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000

Novo Nordisk				X
Bausch			X	
Nestle Health Science			X	
TOPS			X	
Craving Change	X			
WW			X	
Desjardins Insurance			X	
Johnson & Johnson			X	
Medtronic			X	
International Medical Press			X	

* Place an X in the appropriate dollar range cells for each company.

Declaration 14

Name: Canadian Association for Bariatric Physicians & Surgeons

Position: n/a

Date: March 31, 2022

X I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Table 1: Conflict of Interest Declaration for [Canadian Association for Bariatric Physicians and Surgeons]

Company	Check appropriate dollar range*			
	\$0 to \$5,000	\$5,001 to \$10,000	\$10,001 to \$50,000	In excess of \$50,000
Novo Nordisk			X	
Bausch			X	
Nestle Health Science			X	
Pfizer	X			

* Place an X in the appropriate dollar range cells for each company.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	SR0725	
Brand name (generic)	Wegovy (Semaglutide 2.4 mg SC)	
Indication(s)	Obesity	
Organization	Calgary Weight Management Centre	
Contact information ^a	Name: Shahebina Walji	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</p> <p>Obesity is a chronic disease in its own right that has a significant impact on a person's emotional and physical health. We are extremely limited in our options to support our patients. Supporting coverage of Wegovy will improve access to weight management tools for patients who need it most, many of whom are in a lower socioeconomic demographic.</p> <p>While the specific data may not yet be available, our clinical experience has demonstrated a clear improvement in quality of life, pain, and metabolic health – which often includes a reduction in medications for other comorbidities.</p> <p>Supporting coverage of Wegovy would be consistent in the messaging that obesity is a chronic disease requiring multi-factorial treatment options. By not supporting coverage, the indirect messaging is that patients living with obesity are expected to manage their chronic disease on their own using their will power alone. This is not expected of any other chronic disease.</p> <p>Strongly requesting re-consideration of the current recommendation.</p>		
Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not, please provide details regarding the information that requires clarification.		

^a CADTH may contact this person if comments require clarification.

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	<input checked="" type="checkbox"/>
	Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	<input type="checkbox"/>
	Yes	<input checked="" type="checkbox"/>
If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> Clinician 1 Clinician 2 Add additional (as required) 		

C. New or Updated Conflict of Interest Declarations N/A

New or Updated Declaration for Clinician 1	
Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 2

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 3

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 4				
Name	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New or Updated Declaration for Clinician 5				
Name	<i>Please state full name</i>			
Position	<i>Please state currently held position</i>			
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>			
<input type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			
Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0725
Name of the drug and Indication(s)	Semaglutide (Wegovy) as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of <ul style="list-style-type: none"> • 30 kg/m² or greater (obesity), or • 27 kg/m² or greater (overweight) in the presence of at least 1 weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea
Organization Providing Feedback	FWG

1. Recommendation revisions		
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	Major revisions: A change in recommendation category or patient population is requested	<input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested	<input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested	<input type="checkbox"/>
	No requested revisions	X

2. Change in recommendation category or conditions
Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation
Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.

Version: 1.0
 Publication Date: August 2022
 Report Length: 2 Pages

b) Reimbursement conditions and related reasons
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Please provide details regarding the information that requires clarification.

c) Implementation guidance

Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0725
Brand name (generic)	Wegovy (semaglutide)
Indication(s)	Wegovy (semaglutide injection) 2.4 mg is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of: • 30 kg/m ² or greater (obesity), or • 27 kg/m ² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea.
Organization	Gastrointestinal Society
Contact information ^a	Name: Gail Attara
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
<p><i>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</i></p> <p>CADTH's draft recommendation of Do Not Reimburse for semaglutide (Wegovy®) is a devastating and unsafe decision that abandons the needs of thousands of patients living with the chronic disease of obesity.</p> <p>More than a quarter of Canadians (26.8%) are living with obesity and a further 36.6% are overweight. Yet, for such a prevalent chronic disease, there are currently only four medications – liraglutide (Saxenda®), orlistat (Xenical®), semaglutide (Wegovy®), and combination of bupropion and naltrexone (Contrave®) – that Health Canada has approved for chronic weight management. For three of them, CADTH has delivered a Do Not Reimburse recommendation. With obesity stigma and persistent barriers to access and affordability, many individuals might resort to marketed over-the-counter supplements, extreme weight loss programs and crash diets that have little evidence of efficacy and can even be dangerous.</p> <p>As you know, obesity is a multi-factorial, chronic, relapsing disease. It is complex and affected by biological mechanisms that defend against weight loss, rooted in self-preservation. Treatment often requires a combination of diet modification, exercise, behavioral therapy, medications, and/or surgery. Management efforts can be lifelong and there is no one-time cure to end the disease. Please see our video on obesity: https://badgut.org/obesity-video/. It is crucial that patients have access to a variety of treatment options. Individuals are unique, and need a variety of tools to address weight loss, as not all medications work for everyone. However, CADTH has not even recommended any drug for chronic weight management. One respondent in our survey shared that "obesity has been classed as a chronic disease yet there is no funding for medications in the same manner as other chronic diseases."</p>	

If left untreated, the chronic disease of obesity can lead to the development of type II diabetes, high blood pressure, high cholesterol, osteoarthritis, and more, which can worsen patients' quality of life and be costlier to the healthcare system. Please consider providing thousands of patients living with obesity support and hope in managing their disease.

Expert committee consideration of the stakeholder input

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

If not, what aspects are missing from the draft recommendation?

CADTH fails to acknowledge the prevalent role of stigma throughout the healthcare system and its impacts on patient-physician relationships as it uses the argument of the lack of structured weight management programs across Canada. This was the same rationale in CADTH's recommendation for liraglutide, another medication for chronic weight management. As we mentioned in our submission, many of our survey respondents said that they avoid getting medical care as they feel that their physician shames them for being fat. According to one respondent, "I've received the most shame about my weight from doctors to the point that I'm scared to go. They should help, not shame."

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

One of CADTH's main reasons for their recommendation is due to insufficient evidence to support the connection between weight loss and decreased risk for weight-related comorbidities. Although they recognize that an ongoing trial, the SELECT study, will address this evidence gap for cardiovascular conditions, they are not including its findings in their decision. CADTH also recognized the effectiveness of semaglutide for up to 2 years but questioned its efficacy beyond this. Given the severe unmet need for medications, CADTH can adopt real-world evidence (RWE) practices to collect data for this. The use of RWE is a well-recognized approach in other therapeutic areas. It should be applied in obesity, as it is a chronic, relapsing disease.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

^a CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
Name	Gail Attara			
Position	President and Chief Executive Officer, Gastrointestinal Society			
Date	01-09-2022			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add company name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add or remove rows as required	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	SR0725-000	
Brand name (generic)	Wegovy	
Indication(s)	Weight management	
Organization	Obesity Canada	
Contact information ^a	Name: Ian Patton	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</p> <p>Obesity Canada's patient community does not agree with the draft recommendation for the following reasons:</p> <ol style="list-style-type: none"> 1) There is an abundance of evidence that a clinically significant degree of weight reduction in as little as 5%. This degree of weight reduction has been shown time and time again to result in significant improvements in the health and well-being of individuals living with obesity. The Draft recommendation acknowledges that this treatment surpasses that clinically significant threshold of weight reduction with acceptable side effect profile, yet the recommendation to not reimburse rests heavily on the point that the clinical trials did not demonstrate improvements to co-morbid conditions. The treatment is not intended to be a direct treatment for the many co-morbid conditions associated with obesity and was therefore not the focus of the trials, yet, given what we know from other research, individuals who are experiencing 6.21%-14.75% weight reduction (as seen with this particular treatment) can be reasonably expected to see improvements in these co-morbid conditions. 2) Obesity is a complex chronic disease, that is widely misunderstood and while there are evidence-based treatment options AVAILABLE to Canadians living with obesity, they are overwhelmingly NOT ACCESSIBLE. This draft recommendation means that Canadians living with obesity are again left with no reimbursement for any of the available pharmacotherapies and limited options to manage their disease in an effective and evidence-based manner. 3) From our perspective, Wegovy presented a very promising therapeutic option for Canadians living with obesity and the results of the clinical trials have been described as ground-breaking and very strong for the management of obesity, the draft recommendation does not seem to adequately recognize the effectiveness of this treatment for obesity – the condition for which it is used to treat. Rather, the recommendation places the emphasis on secondary endpoints, not the disease itself. 4) Patients living with obesity continue to experience inequalities when it comes to access to obesity treatments. This decision leaves individuals living with obesity with no real options or accessibility to effective obesity treatment. 		
Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not, what aspects are missing from the draft recommendation?		

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p> <p>The medication is used to treat the chronic disease of obesity, the data supports that this treatment is statistically and clinically very effective at treating obesity. The committee needs to clarify what they would consider an effective obesity treatment if not the well established clinically significant threshold of 5% weight reduction. It appears that treatments for obesity management are evaluated differently than treatments for other chronic conditions such as diabetes or hypertension for example. The committee needs to clarify why obesity treatments are viewed differently. The draft recommendation biased against obesity as a chronic disease. Without fair access to evidence-based treatment options, Canadians living with obesity will be left to manage a complex chronic disease on their own and in some cases will turn to non-evidence based and potentially harmful methods to manage obesity.</p>		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p>		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<p>If not, please provide details regarding the information that requires clarification.</p>		

^a CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

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- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
Name	<i>Ian Patton</i>			
Position	<i>Director of Advocacy and Public Engagement</i>			
Date	<i>05/09/2022</i>			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?			No	<input checked="" type="checkbox"/>
			Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.			No	<input type="checkbox"/>
			Yes	<input checked="" type="checkbox"/>
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0725 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	Wegovy (semaglutide)
Indication(s)	As an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of: <ul style="list-style-type: none"> • 30 kg/m² or greater (obesity), or • 27 kg/m² or greater (overweight) in the presence of at least 1 weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea.
Organization	Obesity Matters
Contact information ^a	Priti (Chawla) Karunakaran: [REDACTED]
Stakeholder agreement with the draft recommendation	
1. Does the stakeholder agree with the committee's recommendation.	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.	
<ul style="list-style-type: none"> - While the recommendation acknowledges that treatment with semaglutide resulted in significant body weight reduction (Page 3, under "Rationale for Recommendation", Paragraph 1) and that obesity is associated with an increased risk of a "wide range of comorbidities" (Page 5, under "Background", Paragraph 1), the committee fails to reach the logical conclusion that a <i>decrease</i> in body weight is associated with decreased risk of those same comorbidities. - The recommendation appears to wrongfully focus on "unclear" evidence (Page 3, under "Rationale for Recommendation", Paragraph 1) that semaglutide translates into a reduction in weight-related comorbidities but ignores that it is the <i>reduced weight</i> that leads to a reduction in weight-related comorbidities, not the drug itself. - It is not known whether semaglutide itself reduces the risk of hypertension, sleep apnea or other weight-related comorbidities. But semaglutide does help people achieve a weight that reduces their risk of developing these comorbidities. It is an indisputable fact that people living with a healthy weight are less likely to develop weight-related comorbidities than people living with overweight and obesity, and the committee ignores this reality. - The OM community does not agree that the lack of long-term data (more than two years) should be a reason why semaglutide should not be made available on public drug plans. - Wegovy has been approved by Health Canada, the FDA and in many other countries for the treatment of adults living with obesity and the OM community respects the science on this matter. - It is acknowledged that "structured weight programs are not widely accessible in Canada" (page 4, point 5) but rather than using this failure as a reason to highlight why it is so important to our community to approve the reimbursement, it is used as a justification to not 	

reimburse and maintain the status quo of lack of affordable options for people with obesity (page 12, para 1). This statement denies the fact that these individuals have agency and the wherewithal to know and make lifestyle and behavioural changes and are already patients of metabolic clinics and working with weight management specialists and nutritionists.

Expert committee consideration of the stakeholder input

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

If not, what aspects are missing from the draft recommendation?

- The recommendation does not appear to consider cost as a barrier to proper care.
- The recommendation addresses the need for people living with obesity to improve their quality of life, but the rationale for the recommendation ignores how important cost is when considering if semaglutide should be recommended for reimbursement.
- Obesity Matters submitted survey results from 104 respondents, 88.46% of whom listed drug costs as their number one barrier to their ability to manage a healthy weight. The recommendation fails to address this input and does not appear to properly weigh the impact of high drug costs on access to care.

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

- The implementation issues listed in the recommendation are vague, and it is not clear how relevant some of them are.
- “System and economic issues”, “Care provision issues” and “Considerations for initiation of therapy” (**Page 7, under Drug Program Input**) in particular are all extremely vague potential issues with no clarification provided.
- It is not clear why or how “System and economic issues” or “Care provision issues” are relevant when deciding whether or not to help people access potentially life-saving health care.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

N/A

^a CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

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- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information				
Name	Priti (Chawla) Karunakaran			
Position	Board & Executive Director			
Date	(06-09-2022)			
<input checked="" type="checkbox"/>	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.			
B. Assistance with Providing Feedback				
1. Did you receive help from outside your patient group to complete your feedback?	No	<input checked="" type="checkbox"/>		
	Yes	<input type="checkbox"/>		
If yes, please detail the help and who provided it.				
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	<input checked="" type="checkbox"/>		
	Yes	<input type="checkbox"/>		
If yes, please detail the help and who provided it.				
C. Previously Disclosed Conflict of Interest				
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	x		
	Yes	<input type="checkbox"/>		
D. New or Updated Conflict of Interest Declaration				
3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
AAA Clinical Research	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Danone Canada	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nestle Health Science	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Novo Nordisk Canada	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ODAIA AI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PwC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Priti (Chawla) Karunakaran

Position: Board and Executive Director

Patient Group: Obesity Matters

Date: September 6, 2022